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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,588	11/30/2001	Glenn J. Dorin	012441.00013	3451

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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,588

Applicant(s)

DORIN ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-80,83-128 and 263-291 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 72,74-77,80,83-108,111-128 and 263-291 is/are allowed.
- 6) ☒ Claim(s) 71,73,78,79,109 and 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/3/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to office action dated February 23, 2005, filed on June 3, 2005, is acknowledged. Claims 81, 82 and 129-262 have been canceled. Claim 277 has been amended. New claims 279-291 have been added. Therefore, claims 71-80, 83-128 and 263-291 are currently pending.

Response to Amendments and Remarks

Information Disclosure Statement

Supplemental information disclosure statement is acknowledged.

Claim Rejections - 35 USC § 102

Rejection of claims 71, 73, 111, 114, 115, 118, 127, 128, 270, 271, 273, 275 and 276 as anticipated by Broze et al. is withdrawn in view of Applicants remark and arguments at pages 12-15. The argument is on the basis of, the reference does not teach or suggest the presence of arginine at any concentration in the composition.

Claim Rejections - 35 USC § 103

Rejection of claims 71, 73, 78, 83, 86-89, 95-99, 111, 114, 115, 116, 119, 121, 127, 128, 270, 271, 273, 275, 276 and 279-291 as being unpatentable and under 103(a) as obvious over Broze et al. and further in view of Woog et al. is withdrawn in view of Applicants remarks and arguments on pages 19-21.

Rejection of claims 71, 73, 92, 102, 111, 112, 114, 115, 118, 127, 128, 270, 271, 273, 275-78 95-99, as being unpatentable and under 103(a) as obvious over Broze et al. and further in view of Patel et al. is withdrawn in view of Applicants remarks and arguments on pages 17-19.

Objection to Drawings

The drawings are objected to because Figure 4 describes sequence of TFPI, however no reference is made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:"

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See 37 C.F.R. § 1.181(d). This objection may be overcome by providing sequence identifier followed by actual sequence.

Objection to Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This rejection is maintained because Applicants have failed to provide a Terminal Disclaimer.

Claims 71, 73, 78, 79, 109 and 110 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 9, 33-35, 37 and 41 of U.S. Patent No. 6,323,326. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 71, 73, 78, 109 and 110 are directed to the broadest scope of the solution comprising a polypeptide selected from the group consisting of (i) human TFPI, (ii) ala-human TFPI and (iii) muteins of (i) or (ii). Claims 71, 73, 78, 109 and 110 encompass the TFPI amino acid sequences set forth in claims 1-3, 5 and 9; and encompass the ala-TFPI amino acid sequence set forth in claims 33-35, 37 and 41 of patent '326.

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Claim 71 discloses a solution comprising from 200mM to 300 mM arginine, a polypeptide selected from the group consisting of (i) human TFPI, (ii) ala-human TFPI and (iii) muteins of (i) or (ii). This is an obvious variation of claims 1, and 33 in the patent '326, which discloses an aqueous formulation comprising TFPI and a charged polymer (claim 1 of '326) and wherein TFPI is Ala-TFPI (claim 33).

Claim 73 discloses a solution of claim 71 comprising from 0.2-10 mg/ml of said TFPI. This is an obvious variation of claims 1, 2 and 34 in the patent '326, which discloses an aqueous formulation comprising TFPI wherein the concentration of TFPI is greater than 1 mg/ml (claim 1 of '326), greater than 5 mg/ml (claim 2 of '326) wherein TFPI of claim 2 is Ala-TFPI (claim 34).

Claim 78 discloses a solution comprising more than 0.2 mg/ml of TFPI selected from the group consisting of (i) human TFPI, (ii) ala-human TFPI and (iii) muteins of (i) or (ii) and further comprising a solubilizer selected from the group consisting of sucrose....polyphosphate....and sodium dodecyle sulfate. This is an obvious variation of claim 9 and 41 in the patent '326, which discloses an aqueous formulation comprising TFPI and a charged polymer, wherein charged polymer is polyphosphate (claim 9 of '326) and wherein TFPI is Ala-TFPI (claim 41).

Claim 79 discloses a solution of claim 78 wherein the polypeptide is present in a concentration from 1-20 mg/ml. This is an obvious variation of claim 3 and 35 in the patent '326, which discloses an aqueous formulation of claim 1 ('326), wherein the concentration of TFPI is greater than 10 mg/ml (claim 3 of '326) and wherein TFPI is Ala-TFPI (claim 35).

Claim 109 discloses a solution of claim 108, which is pharmaceutically acceptable. This is an obvious variation of claim 5 and 37 in the patent '326, which discloses an aqueous formulation of claim 1 ('326), which is pharmaceutically acceptable (claim 5 of '326), and wherein TFPI is Ala-TFPI (claim 37).

Claim 110 discloses a solution of claims 78-107, which is pharmaceutically acceptable. This is an obvious variation of claim 5 and 37 in the patent '326, which discloses an aqueous formulation of claim 1 ('326), which is pharmaceutically acceptable (claim 5 of '326), and wherein TFPI is Ala-TFPI (claim 37).

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Thus, claims 71, 73, 78, 79, 109 and 110 in present application and claims 1-3, 5, 9, 33-35, 37 and 41 in the patent '326 are obvious variations of a solution comprising, a polypeptide selected from the group consisting of (i) human TFPI, (ii) ala-human TFPI and (iii) muteins of (i) or (ii), wherein the solution comprises a solubilizer/stabilizer.

Conclusion

Claims 71, 73, 78, 79, 109 and 110 are not allowable. Claims 72, 74-77, 80, 83-108, 111-128 and 263-291 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The

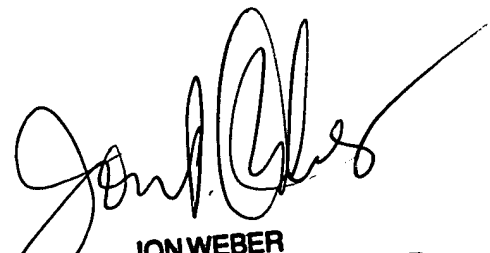
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Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

August 19, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER